

examples, does not enable the full scope of the claims. Applicant traverses this rejection and respectfully requests reconsideration.

Applicant respectfully submits that the Examiner has the initial burden to establish a reasonable basis to question enablement. The Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 USC § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. (MPEP 2164.04).

Patent disclosures are not detailed production blueprints nor are they intended to be. Applicant has disclosed numerous specific working examples of practicing certain embodiments of the claimed subject matter together with the data from those examples. From these examples and the knowledge of persons skilled in this art, it is respectfully submitted that undue or unreasonable experimentation is not needed to practice the presently claimed subject matter. Indeed, the reference cited to Goodman et al. (U.S. 5,550,038) provides evidence that monocots and dicots are known to express mammalian peptides in plant cells.

The mere fact that some experimentation is required and even if that experimentation may be difficult, does not establish a basis for rejecting the claimed subject matter as not enabled. Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 USC § 112. Spectraphysics, Inc. v.

Coherent, Inc. 3 USPQ 2d 1735, 1743 (Fed. Cir. 1987). Accordingly, reconsideration is respectfully solicited.

Rejection under 35 USC 103

Claims 1-18 were rejected under 35 USC 103(a) as being unpatentable over U.S. 5,550,038 to Goodman et al. (hereinafter Goodman). The rejection is traversed and it is respectfully submitted that the claimed subject matter is patentable within the meaning of 35 USC 103(a).

Independent claim 1 is directed to a method for recombinantly and transiently producing a polypeptide in a plant tissue. The method comprises: providing a plant tissue, adding a sample of Agrobacterium containing a nucleotide sequence encoding the polypeptide to the plant tissue, effecting transfer of the nucleotide to the plant tissue, allowing the plant to transiently express the polypeptide, and separating the polypeptide from the mixture. Dependent claims 2-20 further define aspects of the method.

It should be appreciated that the term “transient” means the expression of a recombinant polypeptide after DNA introduction without a requirement for selection of transformed transgenic cells where heterologous DNA is introduced into the plant chromosome. (See, e.g., page 12, lines 8-10 of the specification) According to the claimed subject matter, a nucleotide is delivered and expressed independent of its incorporation in the chromosome. Hence, Applicant has discovered a method that yields an expressed polypeptide without relying on the stable integration into a plant chromosome.

In fact, the claimed method takes advantage of the lack of DNA integration into the chromosome to obtain a large number of non-integrated copies of the transgene in the nucleus to increase expression. This unrecognized and unappreciated step advantageously reduces the time frame of obtaining quantitative amounts of protein from, what would ordinarily be, a minimum of several months to as little as a few days. (See, e.g., Summary of the Invention)

In stark contrast to the claimed subject matter, Goodman teaches that "the construct is introduced into a plant cell to become integrated into the plant genome for expression in the plant cells or plants". (See, e.g., abstract of Goodman) Goodman teaches integrating the nucleotide into the plant chromosome and expressing the nucleotide from a single cell (or small number thereof) that was successfully integrated into the chromosome. Goodman explicitly teaches that these successfully integrated plant cells are provided by a selection procedure (i.e. by killing any plant cells that do not have the integrated DNA). The process continues by proliferating the plant cells (or transgenic plant) so that all cells in the system have the integrated DNA.

The Goodman process can be summarized by a process that delivers DNA to a single cell. Isolating that cell (after integration into the chromosome) and then achieving protein expression from the transformed progeny of that cell after it subsequently divides and proliferates the transgenic DNA (potentially from a single originally delivered DNA). In the Goodman process, DNA expression takes place months after the DNA delivery, even after selection of cells where the DNA is incorporated into the chromosome. In this system, the DNA that is not integrated into the chromosome is lost and those cells die during the selection procedure. Hence it is Applicant's position that there is no direction

in the Goodman process to motivate one of skilled in the art to realistically arrive at the claimed subject matter. Accordingly, reconsideration is respectfully solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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